Senator Manchin Fights to Curb Drug Abuse

May 23, 2012: Senator Manchin included an amendment to the *Food and Drug Administration Safety and Innovation Act* to reschedule hydrocodone. The measure passed by the Senate unanimously.

June 2012: Senator Manchin urged negotiators of a House-Senate compromise of the *Food and Drug Administration Safety and Innovation Act* to support the amendment; however, it was not included in the version of the bill passed in the House of Representatives.

October 29-30, 2012: When Senator Manchin's measure was omitted in the final piece of legislation that was signed into law, he requested that the Food and Drug Administration (FDA) hold a Drug Safety and Risk Management Advisory Committee hearing, which advises the FDA on the abuse potential of drugs and makes recommendations about how they should be controlled.

January 25, 2013: The FDA's own advisory committee voted 19-10 to reclassify the highly addictive drug on the same day that Senator Manchin testified at its committee hearing. Senator Manchin shared several stories from West Virginians who have struggled with hydrocodone addictions or family members whose loved ones overdosed on these painkillers.

February 14, 2013: After numerous phone calls and meetings with FDA officials, Senator Manchin, along with seven additional Members of Congress, sent a letter to FDA Commissioner Hamburg to urge immediate action on rescheduling drugs containing hydrocodone to help curb the prescription drug abuse epidemic, as recommended by the FDA's own advisory board in January 2013.

March 20, 2013: Senator Manchin sponsored the *Safe Prescribing Act*, along with Senator Mark Kirk (R-IL), and Representatives Vern Buchanan (R-FL) and Ed Markey (D-MA), to reclassify hydrocodone painkillers. The bipartisan, bicameral legislation received widespread support from Democrats and Republicans in both legislative chambers, as well as from health care providers, addiction specialists, law enforcement, advocacy groups and victims across the nation.

May 9, 2013: After allotting time for the FDA to implement its own committee's recommendations to reschedule the drug, Senator Manchin sent a letter to Commissioner Hamburg urging the agency to immediately take action and move forward in hydrocodone's reclassification process without delay.

October 9, 2013: Senator Manchin sent a letter to FDA Commissioner Hamburg calling for a full investigation after reports of pay-to-play allegations between the pharmaceutical industry and FDA officials overseeing safety regulations of painkiller medicine. The Washington Post reported that private companies paid as much as $25,000 to participate in FDA advisory panel discussions on federal regulations for prescription painkillers. If FDA officials benefited from this arrangement, there would be a direct conflict of interest that allowed pharmaceutical companies to have undue influence over the FDA's decision-making process, particularly in regards to rescheduling hydrocodone combination drugs.

October 24, 2013: The Department of Health and Human Services (HHS) Secretary Sebelius informed Senator Manchin in October that the Food and Drug Administration (FDA) would recommend rescheduling hydrocodone combination drugs from a Schedule III to a Schedule II controlled substance.

December 6, 2013: Senator Manchin, along with a bipartisan group of Senators, sent a letter to FDA Commissioner Hamburg to question the FDA's approval process of Zohydro, a pure hydrocodone drug, since the FDA's own expert advisory panel voted against the approval of Zohydro by a vote of 11-2. In addition, health experts have repeatedly warned of the potential increase in prescription drug abuse if this highly addictive painkiller becomes publicly accessible.

February 26, 2014: The U.S. Drug Enforcement Administration published a notice of proposed rulemaking (NPRM) to place hydrocodone-containing products from a Schedule III to a Schedule II controlled substance, which kick-starts the reclassification process.

February 26, 2014: Senators Manchin and Vitter sent a letter to the Dean of the School of Medicine and Dentistry at the University of Rochester, Dr. Mark Taubman, regarding reports that the university hosted pay-to-play meetings between pharmaceutical manufacturers and officials at the FDA who oversee safety regulations of painkiller medicine. Industry reportedly paid upwards of $25,000-$35,000 per conference to have a seat at the table with these FDA officials.

March 10, 2014: Senator Manchin sent a letter to HHS Secretary Sebelius requesting to overturn the FDA's approval of Zohydro to keep this dangerous and highly addictive substance off the market.

March 10, 2014: Senators Manchin, Vitter and Lee sent a letter to HHS Inspector General Daniel Levinson to ask for an investigation into reports that pharmaceutical drug companies paid $25,000 - $35,000 to attend private meetings between FDA officials and the University of Rochester, which potentially influence prescription drug testing and approval.

March 13, 2014: Senator Manchin introduced legislation to ban Zohydro.

April 29, 2014: Senator Manchin submitted a public comment to the Drug Enforcement Administration (DEA) encouraging the agency to reschedule hydrocodone-combination drugs from a Schedule III to a Schedule II controlled substance.

May-July 2014: Senator Manchin called the CEOs at CVS Pharmacy, Kmart, Kroger, Rite-Aid, Walgreens and Walmart requesting that they stop selling single-ingredient pseudoephedrine that is used to make illegal methamphetamine at their pharmacies.

July 2014: After being urged by Senator Manchin, CVS, Walgreens, Kmart and Rite-Aid stores in West Virginia stopped selling single-ingredient, non-tamper resistant pseudoephedrine that is used to make illegal methamphetamine. Additionally, Kroger stores in West Virginia announced they would limit the sale of single-ingredient pseudoephedrine.

August 22, 2014: The U.S. Drug Enforcement Administration (DEA) officially announced the final rule to reschedule hydrocodone-combination drugs, a tremendous legislative victory for Senator Manchin and the entire country.

January 28, 2015: Senator Manchin sent individual letters to members of the West Virginia Legislature encouraging the body to pass legislation implementing the West Virginia Board of Pharmacy's recommendations to curb the tide of methamphetamine production in the state. The Board's recommendations include rescheduling pseudoephedrine products as a controlled substance that requires a prescription to obtain, lowering the monthly pseudoephedrine sales limit to 3.6g and lowering the annual pseudoephedrine sales limit to 24g.

March 26th – Senator Manchin introduced an amendment, which was included in the final FY2016 Congressional Budget, to encourage Congress to invest in efforts to combat meth abuse.

April 15, 2015: Senators Manchin and Vitter introduced the *FDA Accountability for Public Safety Act* to hold the Food and Drug Administration (FDA) accountable for opioid drugs approved by the agency. The legislation would ensure that experts' voices are heard when the FDA is considering new, dangerous opioid medications.

May 18, 2015: Senator Manchin, along with nine of his Senate colleagues, sent a letter to U.S. Attorney General Loretta Lynch calling for the reinstatement of National Drug Take-Back Day Program.

May 21, 2015: Senators Manchin and Scott launched the Prescription Drug Abuse Caucus in an effort to raise awareness and show that the U.S. Senate is serious about helping the millions of American families whose lives have been torn apart by prescription drug abuse.

May 21, 2015: Senator Manchin introduced the *Prescription Drug Abuse Prevention and Treatment Act* to improve efforts to prevent and treat prescription drug abuse.

May 23, 2015: Senator Manchin sent letters to the CEOs of 13 drug distributors asking for the release of records that would show the number of prescription painkillers the companies have shipped to West Virginia over the past decade.

August 17, 2015: Senator Manchin applauded the White House Office of National Drug Control Policy (ONDCP) for granting additional High Intensity Drug Trafficking Areas (HIDTAs) funding to address the recent surge in heroin trafficking and overdoses and to help reduce drug abuse.

August 17, 2015: Senator Manchin sent a letter to the Acting Commissioner of Food and Drugs at the U.S. Food and Drug Administration (FDA), Dr. Stephen Ostroff, condemning the agency's decision to approve OxyContin for use for children as young as 11 years old.

September 9, 2015: Senators Manchin, Kaine and Mark Warner sent a letter to the Health, Education, Labor and Pensions (HELP) Committee Chairman Lamar Alexander (R-TN) and Ranking Member Patty Murray (D-WA) calling for an investigation into the Food and Drug Administration's (FDA) decision to approve OxyContin for use by reschedule hydrocodone-combination drugs, a tremendous legislative victory for Senator Manchin and the entire country.

January 28, 2015: Senator Manchin sent individual letters to members of the West Virginia Legislature encouraging the body to pass legislation implementing the West Virginia Board of Pharmacy's recommendations to curb the tide of methamphetamine production in the state. The Board's recommendations include rescheduling pseudoephedrine products as a controlled substance that requires a prescription to obtain, lowering the monthly pseudoephedrine sales limit to 3.6g and lowering the annual pseudoephedrine sales limit to 24g.

March 26" 2015: Senator Manchin introduced an amendment, which was included in the final FY2016 Congressional Budget, to encourage Congress to invest in efforts to combat meth abuse.

April 15, 2015: Senators Manchin and Vitter introduced the *FDA Accountability for Public Safety Act* to hold the Food and Drug Administration (FDA) accountable for opioid drugs approved by the agency. The legislation would ensure that experts' voices are heard when the FDA is considering new, dangerous opioid medications.

May 18, 2015: Senator Manchin, along with nine of his Senate colleagues, sent a letter to U.S. Attorney General Loretta Lynch calling for the reinstatement of National Drug Take-Back Day Program.

May 21, 2015: Senators Manchin and Scott launched the Prescription Drug Abuse Caucus in an effort to raise awareness and show that the U.S. Senate is serious about helping the millions of American families whose lives have been torn apart by prescription drug abuse.

May 21, 2015: Senator Manchin introduced the *Prescription Drug Abuse Prevention and Treatment Act* to improve efforts to prevent and treat prescription drug abuse.

May 23, 2015: Senator Manchin sent letters to the CEOs of 13 drug distributors asking for the release of records that would show the number of prescription painkillers the companies have shipped to West Virginia over the past decade.

August 17, 2015: Senator Manchin applauded the White House Office of National Drug Control Policy (ONDCP) for granting additional High Intensity Drug Trafficking Areas (HIDTAs) funding to address the recent surge in heroin trafficking and overdoses and to help reduce drug abuse.

August 17, 2015: Senator Manchin sent a letter to the Acting Commissioner of Food and Drugs at the U.S. Food and Drug Administration (FDA), Dr. Stephen Ostroff, condemning the agency's decision to approve OxyContin for use for children as young as 11 years old.

September 9, 2015: Senators Manchin, Kaine and Mark Warner sent a letter to the Health, Education, Labor and Pensions (HELP) Committee Chairman Lamar Alexander (R-TN) and Ranking Member Patty Murray (D-WA) calling for an investigation into the Food and Drug Administration's (FDA) decision to approve OxyContin for

use by children as young as 11-years-old and an examination of the rise in the opioid misuse, abuse and consequent overdose deaths.
November 18, 2015: Senator Manchin sent a bipartisan letter to Senate appropriators to request that any final appropriations package include necessary resources for critical substance abuse prevention and treatment services.

December 23, 2015: Senator Manchin sent a letter to the U.S. Department of Health and Human Services (HHS) Secretary Sylvia Mathews Burwell urging the agency to support the release of the Centers for Disease Control and Prevention's (CDC) Draft Guidelines for Opioid Prescribing, which have been delayed in response to pressure from outside groups, including the Food and Drug Administration (FDA).

January 14, 2016: Senator Manchin applauded the designation of Jefferson County as a High Intensity Drug Trafficking Area. The move enables Jefferson County to receive federal resources to further the coordination and development of drug control efforts among federal, state, and local law enforcement officials. It also allows local agencies to benefit from ongoing HIDTA-coordinated initiatives working to reduce drug use and its consequences across the United States.

January 26, 2016: Senator Manchin applauded the drastic reduction of opioid prescriptions by 26.3 million, or 1.1 billion tablets, since moving the hydrocodone-combination drugs from Schedule III to Schedule II. The research, conducted by U.S. Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA), was published in a JAMA Internal Medicine report.

January 27, 2016: Senator Manchin announced plans to filibuster the Obama Administration's nominee, Robert Califf, to be the next Commissioner of the U.S. Food and Drug Administration (FDA) because of his strong ties to the pharmaceutical industry. The Senator stated that he would use his time during the filibuster to read letters on the Senate floor from West Virginians that are suffering from the devastating effects of opioid abuse themselves, in their families and in their communities.